WO9423777

Publication Title:

INTRADERMAL INJECTION DEVICE

Abstract:

A device (10) for administering, including self-administering, a metered dose of a liquid medicament (23) intradermally or subcutaneously comprises means (12, 27', 30', 35) for creating a vacuum so as to secure the device (10) to the skin during medicament delivery, means (32) for penetrating one or more skin layers to a desired depth and delivering the medicament and means (12, 27', 30', 35) for releasing the vacuum for removal of the device (10) following medicament delivery. The device (10) can be in the form of a disposable, pre-filled product for once-off use. The device (10) provides a convenient method of medicament delivery for increasing patient compliance.

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 5/42	A1	(11) International Publication Number: WO 94/23777
		(43) International Publication Date: 27 October 1994 (27.10.94)

(21) International Application Number: PCT/IE94/00020

(22) International Filing Date: 7 April 1994 (07.04.94)

(30) Priority Data:
930274 8 April 1993 (08.04.93) IE

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(81) Designated States: AU, CA, JP, NZ, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

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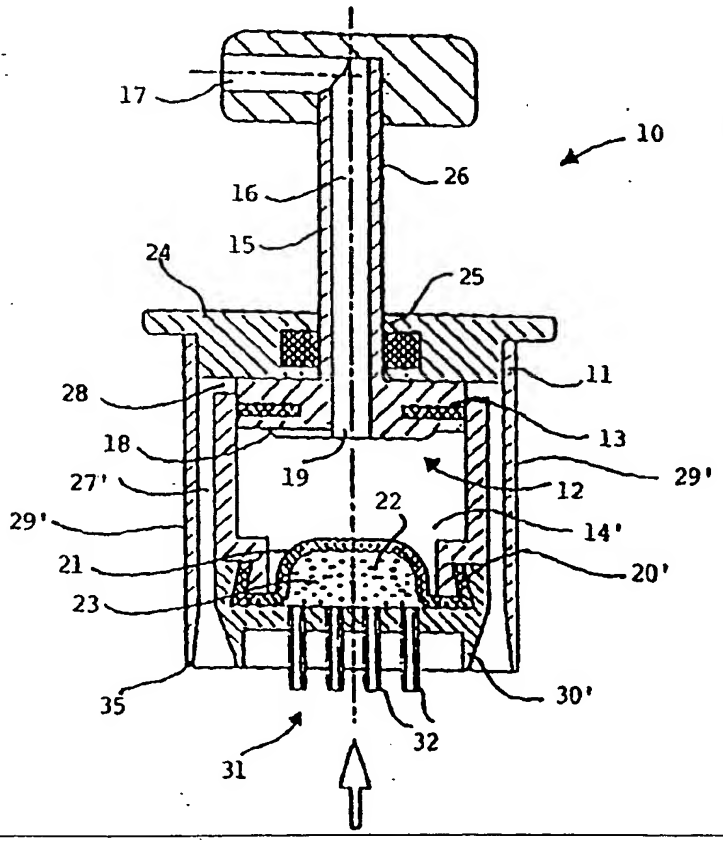
A device (10) for administering, including self-administering, a metered dose of a liquid medicament (23) intradermally or subcutaneously comprises means (12, 27', 30', 35) for creating a vacuum so as to secure the device (10) to the skin during medicament delivery, means (32) for penetrating one or more skin layers to a desired depth and delivering the medicament and means (12, 27', 30', 35) for releasing the vacuum for removal of the device (10) following medicament delivery. The device (10) can be in the form of a disposable, pre-filled product for once-off use. The device (10) provides a convenient method of medicament delivery for increasing patient compliance.



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Description

INTRADERMAL INJECTION DEVICE

Technical Field

This invention relates to a device for administering intradermally a medicament in liquid form.

The use of the term "intradermal" herein is intended to embrace subcutaneous.

Background Art

Many drugs, active ingredients or medications, hereinafter referred to collectively as medicaments, require administration by injection. This mode of administration tends to be inconvenient and also painful. Patients may be required to self-administer a medicament, such as insulin in the case of diabetics, and various attempts have been made to make this mode of administration more convenient, thereby, increasing patient compliance. Thus, "pen" type injectors have been proposed.

There is a need for a device which can be used to automatically inject a metered dose of a medicament intradermally with the minimum of trauma. Such a device should ideally include a needle or needles which enter the skin to a predetermined depth and allow precise penetration of the skin by the patient.

Disclosure of the Invention

The invention provides a device for administering intradermally a metered dose of a medicament in liquid form, said device comprising means for creating a vacuum so as to secure the device to the skin during medicament delivery, means for penetrating one or more skin layers and delivering said metered dose and means for releasing said

vacuum for removal of the device following delivery of the metered dose.

The device according to the invention can be used with a minimum of trauma by patients as well as by medical and nursing staff, to administer a range of medicaments, including peptides and polypeptides, by the intradermal route as hereinbefore defined.

Preferably, the means for creating the vacuum comprises a piston arrangement and an associated system of air channels.

Further, preferably, the means for penetrating the or each skin layer comprises a plurality of hollow needles in communication with a reservoir for the medicament.

The creation of the vacuum can cause the skin to be drawn towards, and penetrated by, said penetration means.

In one embodiment, the vacuum is created circumferentially of the penetrating means. For example, the vacuum can be generated circumferentially of a housing for the device.

In the case when the penetrating means comprises a plurality of hollow needles, a vacuum can be created circumferentially of each needle defining said penetrating means.

The piston arrangement, when such is present, is preferably actuated by a plunger mechanism integral with the piston. Further, preferably, the piston impinges on a displaceable membrane defining a boundary wall of the reservoir so as to expel the contents of the reservoir through the penetrating means when the piston is depressed. Further, preferably, the plunger has an internal air duct which is open to the atmosphere.

When it is desired to release the vacuum and, thereby, the device from the skin of a patient following administration of the medicament, the piston is retracted.

The penetrating means can be movable within the device, such that when the vacuum is generated, said penetrating means is simultaneously or sequentially displaced towards the skin for penetration thereof.

According to a preferred embodiment, actuation of the device simultaneously creates the vacuum and causes movement of the skin penetrating means for penetration of the skin.

For example, following application of the device to the skin and actuation thereof, the vacuum generated can draw the skin against a plate structure in the device disposed on a skin-contacting surface thereof. The plate structure then maintains the skin in position while a set of needles is caused to descend and pass through a plurality of apertures in said plate structure and enter the skin to a predetermined depth.

Alternatively, a set of needles is fixed in position on such a plate structure and the act of drawing the skin against the plate causes the needles to penetrate the skin. The medicament is then delivered as a single dose through the set of needles.

The withdrawal of the needles from the skin can release the vacuum or *vice versa*.

The device according to the invention is preferably in the form of a disposable pre-filled product for once-off use, although the device can be readily adapted for continued use by the provision of filling means for replenishing the reservoir. In the case of a refillable device, the device is suitably provided with means for indicating when a quantity, corresponding to one or more metered doses, has been inserted therein.

The medicament can have almost any viscosity, provided that it can be dispensed through the penetrating means at a rate which is pharmaceutically effective and acceptable.

The penetrating means will suitably be manufactured from medical-grade stainless steel. However, the penetrating means can also be composed of a suitable inert plastics material.

Other parts of the device may also be manufactured from suitable plastics materials.

The device according to the invention is suitable for the administration, including self-administration, of a wide range of medicaments, including peptides and polypeptides. The device according to the invention is especially suitable for the administration of insulin.

The device according to the invention is also suitable for the administration of vaccines in methods of vaccination.

The device according to the invention can be used to inject a medicament intradermally or subcutaneously automatically as desired by suitable adjustment of the length of the needles or the extent to which the needles or other penetrating means are movable relative to or within the device.

The device according to the invention allows for precise penetration of the skin which is an advantage over currently available automatic injection devices.

The device according to the invention can also be used to inject controlled release formulations, suitably in a lipophilic base, allowing for convenient subcutaneous injection of depot formulations.

The device may be enclosed in a sterilised package until required for use. Furthermore, the needles or other penetrating means will

normally be either covered by a peel-off strip or stuck in an impermeable pad to prevent the medicament from leaking out of the device while in storage.

The invention will be further illustrated by the following description of embodiments thereof given by way of example only with reference to the accompanying Drawings in which like parts are indicated by like reference numerals.

Brief Description of the Drawings

In the accompanying Drawings:

Fig.1 is a front elevation in section of a first embodiment of the device according to the invention;

Fig. 2 is a plan view of the device of Fig. 1 taken on the line II-II;

Fig. 3 is a front elevation in section of a second embodiment of the device according to the invention; and

Fig. 4 is a plan view of the device of Fig. 3 in the direction of the arrow.

Modes for Carrying Out the Invention

Referring to Figs. 1 and 2 of the Drawings, there is indicated generally at 10, a device for administering intradermally to a patient a metered dose of a medicament in liquid form. The device 10 comprises a housing 11 and a piston arrangement, indicated generally at 12, comprising a piston 13 movable in sealing engagement within a hollow chamber 14 disposed internally of the housing 11. The piston 13 is provided with an integral plunger mechanism 15 for actuation by the person administering the medicament. The plunger 15 has an internal airway 16 which is substantially L-shaped and which

communicates with the atmosphere *via* an outlet 17. End 18 of the piston 13, which travels within the chamber 14, serves to close the end of the chamber 14 distal from the skin, in use, apart from a second outlet 19 of the airway 16. The end of the chamber 14 proximal to the skin, in use, is defined by an elastomeric membrane 20 defining a boundary wall 21 of a reservoir 22 for the medicament 23.

The piston arrangement 12 is similar to that used in a conventional hypodermic syringe and thus end 18 of piston 13 which travels within chamber 14 has a circumferentially extending flexible grooved sealing means.

The housing 11 has a cap 24 with an aperture 25 through which shaft 26 of the plunger mechanism 15 passes in sealing engagement therewith.

An air chamber 27 which communicates *via* extension 28 with the space above end 18 of the piston 13 when the piston is depressed is disposed intermediate walls 29 of the housing 11 and the walls of the chamber 14 and is continuous within a skin-contacting part 30 of the housing 11 containing penetrating means 31 comprised of a plurality of needles 32. The air chamber 27 is also in communication with an aperture 33 surrounding each needle 32.

The air chamber 27 can be replaced by a plurality of narrow bore air chambers, typically four, spaced equidistantly about the circumference of the device 10 and being continuous with the space above end 18 of the piston 13 when the piston is depressed and with the skin-contacting part 30.

The device 10 is provided with a circumferentially extending elastomeric sealing ring 34 for engagement with the skin in use.

In use, when it is desired to administer a liquid medicament such as insulin, the person administering the medicament, who may be the patient, selects the site on the skin at which the medicament is to be

administered. The device 10 is applied to the skin, the plunger mechanism 15 is depressed in the direction of the skin, causing the piston 13 to move towards the membrane 21.

The hollow chamber 14 is open to the atmosphere *via* outlet 17. Depression of the piston 13 causes a reduction in pressure in space 28 and causes air to be sucked into said space *via* the air chamber 27, resulting in the creation of a vacuum at the site of application of the device 10. The creation of the vacuum causes the skin to be drawn towards and penetrated by the needles 32. As the plunger is fully depressed, the medicament 23 is delivered through the needles 32 in response to the action of the piston 13 depressing the membrane 20 which forces the medicament 23 out of the reservoir 22 and into the needles 32 followed by intradermal delivery. To release the device 10 from the skin (not shown) following medicament delivery, the piston 13 is retracted releasing the vacuum and thereby releasing the device 10.

Best Mode for Carrying Out the Invention

Referring to Figs. 3 and 4 of the Drawings there is illustrated a modification of the device 10 depicted in Fig. 1 and wherein like parts are accorded like reference numerals.

The hollow chamber 14' and the skin-contacting part 30' each has a slightly different shape relative to the hollow chamber 14 and the skin-contacting part 30, respectively, of the embodiment depicted in Fig. 1. Likewise, the membrane 20' *in situ* has a shape dictated by the interengaging parts 14' and 30'.

In addition to skin-contacting part 30', there is also provided a peripherally-extending flange 35 which, in use, rests on the skin (not shown). An air chamber 27' is formed intermediate walls 29' of the housing 11 and externally of the hollow chamber 14' and the skin-contacting part 30'.

In the embodiment of Fig. 3, the needles 32 are not each provided with an aperture in contact with the air chamber 27'. Rather, when the flange 35 engages the skin, in use, and the piston 13 is depressed, air is sucked from the air chamber 27' into space 28 above piston 13, so as to create a vacuum circumferentially and externally of the part of the device 10 housing the needles 32. The creation of the vacuum causes the device 10 to be held firmly in contact with the skin during delivery of the medicament. To release the device 10, the piston 13 is retracted in the same manner as for the embodiment depicted in Fig. 1.

Claims: -

1. A device for administering intradermally a metered dose of a medicament in liquid form, said device comprising means for creating a vacuum so as to secure the device to the skin during medicament delivery, means for penetrating one or more skin layers and delivering said metered dose and means for releasing said vacuum for removal of the device following delivery of the metered dose.

2. A device according to Claim 1, wherein the means for creating the vacuum comprises a piston arrangement and an associated system of air channels.

3. A device according to Claim 1 or 2, wherein the means for penetrating the or each skin layer comprises a plurality of hollow needles in communication with a reservoir for the medicament.

4. A device according to Claim 3, wherein the creation of the vacuum causes the skin to be drawn towards, and penetrated by, the needles.

5. A device according to any preceding claim, wherein the vacuum is created circumferentially of the penetrating means.

6. A device according to Claim 4, wherein a vacuum is created circumferentially of each needle defining said penetration means.

7. A device according to any one of Claims 2 and 3-6 when dependent on Claim 2, wherein the piston arrangement is actuated by a plunger mechanism integral with the piston.

8. A device according to Claim 7 when dependent on Claim 3, wherein the piston impinges on a displaceable membrane defining a boundary wall of the reservoir so as to expel the contents of the reservoir through the penetrating means when the piston is depressed.

9. A device according to Claim 8, wherein the piston and plunger arrangement has an internal air duct which is open to the atmosphere.

10. A device according to Claim 8 or 9, wherein the piston is retracted so as to release said vacuum.

11. A device according to any preceding claim, wherein the means for penetrating the or each skin layer is moveable within the device.

12. A device according to Claim 11 when dependent on Claim 2, wherein actuation of the piston causes movement of the means for penetrating the skin.

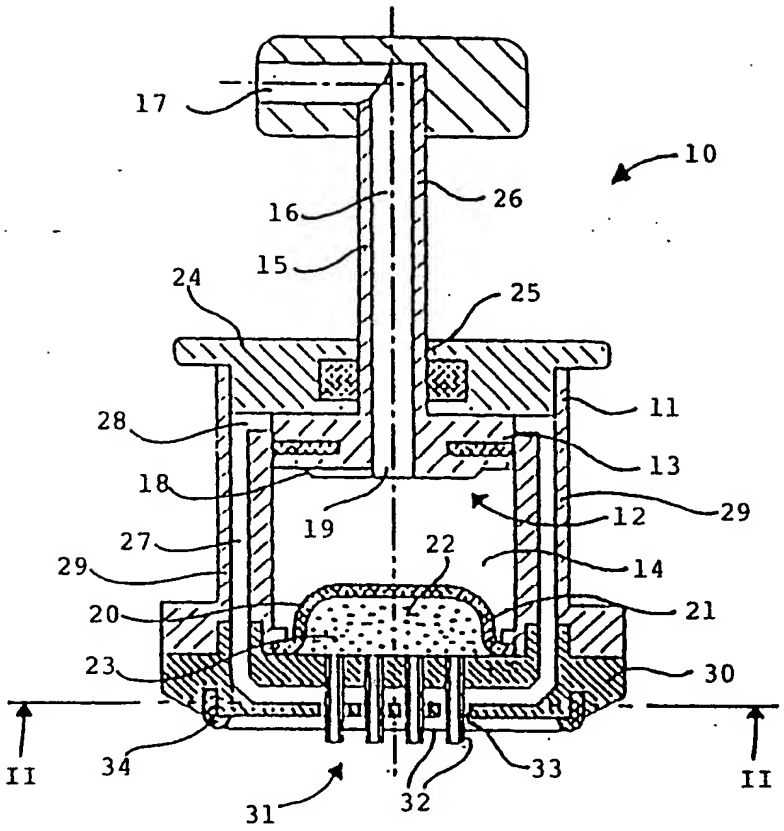
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Fig. 1

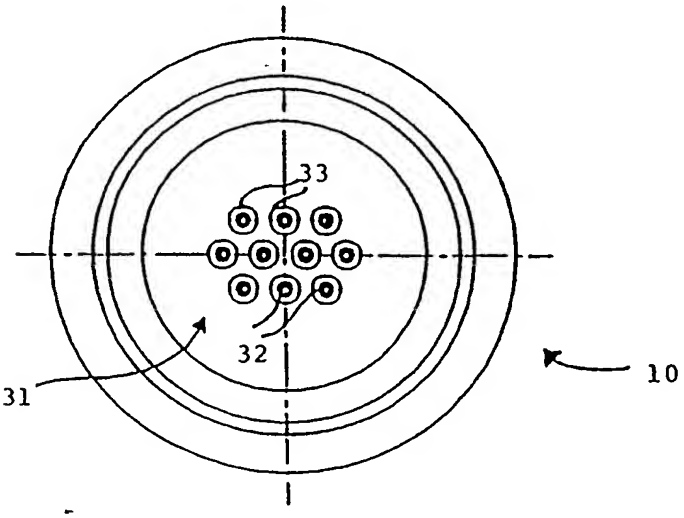
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Fig. 2

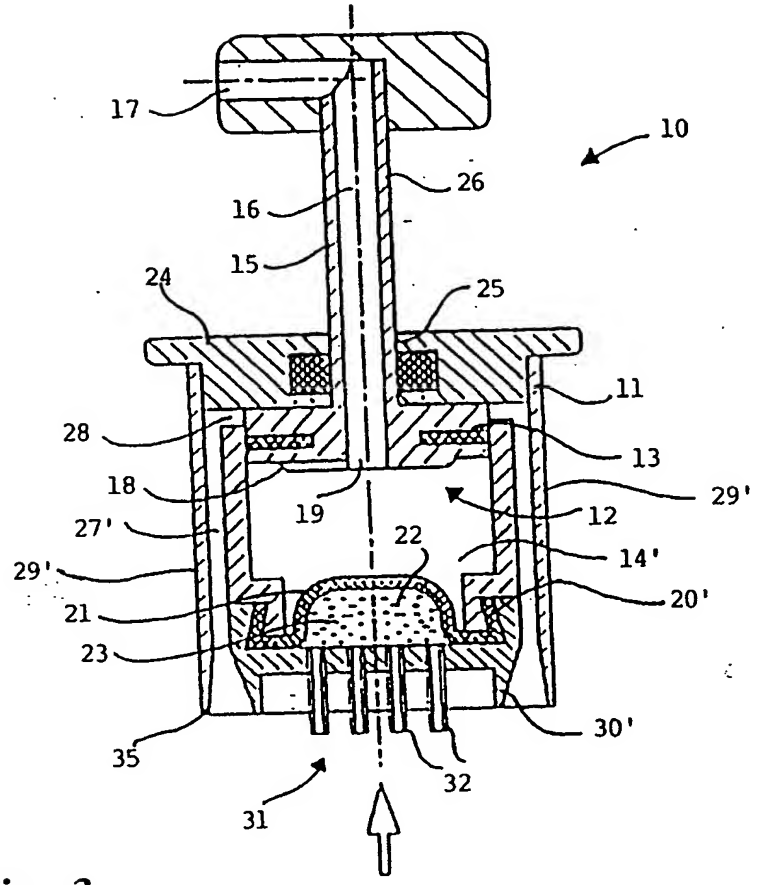
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Fig. 3

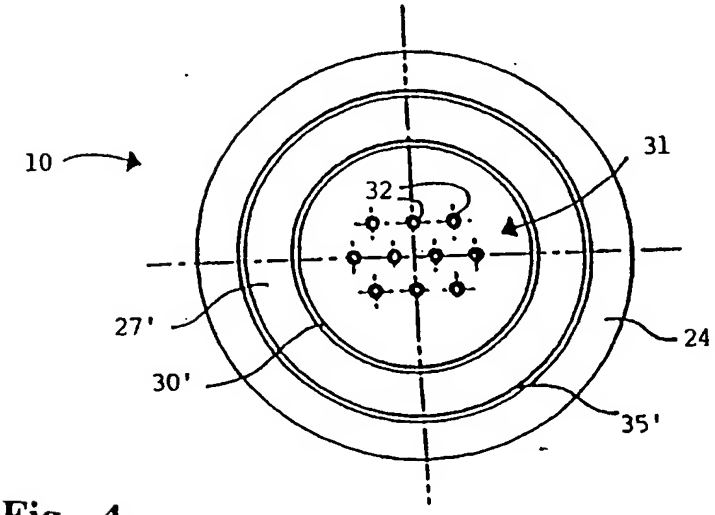
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Fig. 4

INTERNATIONAL SEARCH REPORT

Inten ıal Application No
PCT/IE 94/00020

A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 A61M5/42

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	DE,A,30 19 589 (WAGNER) 15 January 1981 see page 10, line 1 - page 11, paragraph 1; figures 1,2	1,2,5, 10,11 3,4,6
Y	FR,A,2 041 605 (SHOZO NARUSAWA) 29 January 1971 see page 3, line 15 - line 24; figures	3,4,6
X	GB,A,371 305 (DEMARCHI) 12 May 1932 see page 1, line 61 - page 2, line 14; figures	1,5,11
X	US,A,2 743 723 (HEIN) 1 May 1956 see column 3, line 9 - line 65; figures	1,5,11
A	GB,A,992 424 (VACUUM EXTRACTOR A.B) 19 May 1965	

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